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dosage form, the route of administration, the trade name of the product, the name of the application holder, and the strength or potency of the product. The listing also includes, for each active ingredient in a particular dosage form for which there is more than one approved application, an evaluation of the therapeutic equivalence of the drug products covered by such applications.

(b) Other computer printouts containing IND and NDA information are available to the extent that they do not reveal data or information prohibited from disclosure under §§ 20.61, 312.130, and 314.430 of this chapter.

[42 FR 15616, Mar. 22, 1977, as amended at 45 FR 72608, Oct. 31, 1980; 46 FR 8457, Jan. 27, 1981; 54 FR 9038, Mar. 3, 1989; 64 FR 399, Jan. 5, 1999]

§ 20.118 Advisory committee records.

All advisory committee records shall be handled in accordance with the rules established in parts 10, 12, 13, 14, 15, 16, and 19 of this chapter.

§ 20.119 Lists of names and addresses.

Names and addresses of individuals in Food and Drug Administration records shall not be sold or rented. Names and addresses shall not be disclosed if disclosure is prohibited as a clearly unwarranted invasion of personal privacy, e.g., lists of names and home addresses of Food and Drug Administration employees, which shall not be disclosed under §20.110.

PART 21—PROTECTION OF PRIVACY

Subpart A—General Provisions

Sec.

21.1 Scope.

21.3 Definitions.

21.10 Policy concerning records about individuals.

Subpart B—Food and Drug Administration Privacy Act Record Systems

- 21.20 Procedures for notice of Food and Drug Administration Privacy Act Record Systems.
- 21.21 Changes in systems and new systems.

Subpart C—Requirements for Specific Categories of Records

- 21.30 Records of contractors.
- 21.31 Records stored by the National Archives and Records Administration.
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Subpart D—Procedures for Notification of and Access to Records in Privacy Act Record Systems

- 21.40 Procedures for submitting requests for notification and access.
- 21.41 Processing of requests.
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- 21.43 Access to requested records.
- 21.44 Verification of identity.
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Subpart E—Procedures for Requests for Amendment of Records

- 21.50 Procedures for submitting requests for amendment of records.
- 21.51 Responses to requests for amendment of records.
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- 21.53 Notation and disclosure of disputed records.
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Subpart F—Exemptions

21.60 Policy.

21.61 Exempt systems.

21.65 $\,$ Access to records in exempt systems.

Subpart G—Disclosure of Records in Privacy Act Record Systems to Persons Other Than the Subject Individual

- 21.70 Disclosure and intra-agency use of records in Privacy Act Record Systems; no accounting required.
- 21.71 Disclosure of records in Privacy Act Record Systems; accounting required.
- 21.72 Individual consent to disclosure of records to other persons.
- 21.73 Accuracy, completeness, timeliness, and relevance of records disclosed from Privacy Act Record Systems.
- 21.74 Providing notice that a record is disputed.
- 21.75 Rights of legal guardians.

AUTHORITY: 21 U.S.C. 371; 5 U.S.C. 552, 552a.

Source: 42 FR 15626, Mar. 22, 1977, unless otherwise noted.